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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/976,872
Filing Date: October 12, 2001
Appellant(s): TORANTO ET AL.

David A. Casimir
For Appellant

EXAMINER'S ANSWER

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-15 and 18-27 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

3,875,013	MANAUTOU	04-1975
6,248,598	BOGEMA	06-2001
5,494,831	KINDLER	02-1996

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4, and 11are rejected under 35 U.S.C. 102(b) as being anticipated by Manautou et al (USP#3,875,013).

Manautou et al teaches a test that provides for detecting the fertile period or the presence of pregnancy in a female. In one embodiment, the saliva of a female is tested orally, in which her tongue wets the test paper and waits about 20 minutes before forming a color. The test strips are impregnated with reagents for the practice of the invention as recited in claims 1-6 (col. 3, lines 20-25). The test strips is then compared to a standard color card that has a series of color spots similarly developed from known concentrations of the color compound p-nitrophenol (chromogen) as recited in claims 2, and 11 (col. 3, lines 39-58).

Claims 5-6, 8-15, and 18-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manautou et al in view of Stuart C. Bogema (USP#6,248,598).

The teachings of Manautou et al are set forth above and differ from the instant invention by not specifically pointing out that the reaction site comprise of an antibody or the length of time reaction site is held in the mouth of the subject.

However, Stuart C. Bogema teaches a device that provides a rapid analysis of saliva samples while also providing a convenient assay method that can be used by non-laboratory personnel without risk of user errors (see abstract). A solid support (strip) made of a suitable absorbent material is inserted into the patient's mouth that

provides for sufficient absorption of saliva for about 10-120 seconds (col. 7, lines 15-65). A portion of the solid support (strip) includes a visual reading area on which is directly bound a binding partner, a protein such as an antibody that specifically binds an analyte that comprise of a colored label (col. 8, lines 12-23). The results can be seen with the naked eye (col. 8, lines 52-54).

It would have been obvious to one of ordinary skill in the art to incorporate an antibody as taught by Stuart C. Bogema and utilize it in the reaction site of the test strip as taught by Manautou et al to specifically bind the analyte being detected in the saliva. It would have also been obvious to one of ordinary skill in the art to modify the test strip of Manautou et al to perform an assay test quickly and simply thereby eliminating the need for a technician or a laboratory setting that should afford benefits both in terms of convenience and reduced costs. With respect to claims 20-27, which are features of remaining dependent claims that are either specifically described by the references (e.g., ethanol, methanol detection col. 11, line 11) or constitute obvious variations which are routinely modified in the art and which have not been described as critical to the practice of the invention, it would have been further obvious to one having ordinary skill the art at the time the invention was made to modify the method of Manautou et al to detect any known analyte of interest, especially since it has been held that the provision of adjustability, where needed, involves only routine skill in the art. In re Stevens, 101 USPQ 284 (CCPA 1954). Absent evidence to the contrary, the detection of known analytes in the instant invention is viewed as routine optimization in prior art. With respect to claims 18-19, it would have been further obvious that the teachings of the

instant reference would encompass these known safety features, especially when patient is undergoing oral testing for detection of an analyte wherein said test utilizes a chromogen, as taught Manautou et al one skilled in the art would assume that a chromogen that is used on a patient's tongue, a non-toxic, non-irritating and one that is not a known carcinogen will be utilized.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manautou et al in view Andrew Kindler (USP#5,494,831).

The teachings of Manautou et al are set forth above and differ from the instant claim in not teaching the use of a biosensor.

However, Andrew Kindler teaches an electrochemical immunosensor (biosensor) which uses electrical signals to measure binding events. Signal generating means develop an electrical signal at the sensing electrode such that a response current is produced through the sensing electrode. The response current has measurable signal that are dependent upon the number of complexes formed within the sample concentration (see abstract).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Manautou et al to include the use of a biosensor as taught by Andrew Kindler to not only detect the analyte in a sample, but to also measure quantities of the binding events (col. 3, lines 30-40).

(11) Response to Argument

Patentability of Group I, Claims 1-4 and 11

Applicant's argument that examiner did not properly consider the evidence presented in NTP Chemical Repository Data Sheet that makes references to the toxicity of p-nitrophenol is noted but not found to be persuasive.

In response, the applicant did not assert at what levels that the chromogen p-nitrophenol was toxic; therefore the examiner relied on the teaching of the prior art, which taught usage of the chromogen on oral test strips at low levels. It was the Examiner's position that certain levels of any chemical can be toxic. For example, everyday mouthwash can be toxic if swallowed. The fact that p-nitrophenol can be toxic at certain levels; this chromogen can also be non-toxic at certain levels. For instance, Applicant quotes information from the U.S Department of Health and Human Services that confirms p-nitrophenol is toxic in adult rats at approximately ***five thousands of an ounce (0.005)***. The prior art of Manutou et al teaches that ***0.1 to 0.5 ml*** of a non-toxic buffered substrate consisting of ***0.1M p-nitrophenyl-n acetyl-B-d-glucosaminide (p-nitrophenol)*** was impregnated on a test strip and placed on a patient's tongue for pregnancy testing (column 3, lines 20-59 and column 4, lines 63-68). The Examiner has calculated and performed conversion factors of 0.1ml of 0.1M of p-nitrophenyl-*N*-acetyl-β-*d*-glucosaminide to ounces that resulted in 0.000245 ounces. Therefore, the p-nitrophenol used in the pregnancy strip taught by Manatou et al is less than the amount confirmed to be toxic (.005 ounces) by the Department of Health and Human Services.

In the Examiner's view, 0.000245 ounces of p-nitrophenol chromogen meet the limitation of non-toxic recited in the instant invention, and therefore the above claims are considered anticipated by Manautou et al.

Patentability of Group II, Claims 5-6, 8-15 and 18-27

Applicant argument that the prior art of Manautou et al and Bogema et al alone or in combination contains no teaching of a non-toxic chromogen for oral testing is noted but not found to be persuasive for reasons for reasons addressed in the above arguments.

Patentability of Group III, Claim 7

Applicant argument that the prior art of Manautou et al and Kindler et al alone or in combination contains no teaching of a non-toxic chromogen for oral testing is noted but not found to be persuasive for reasons for reasons addressed in the above arguments.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Patent Examiner
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January 4, 2005

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